



DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of an Anti-Mesothelin Chimeric Antigen Receptor (CAR) for the Treatment of Mesothelin-Expressing Human Cancers

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to Evotec International GmbH (Evotec), located in Hamburg, Germany.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: David A. Lambertson, Ph.D., Technology Transfer Manager, NCI Technology Transfer Center, Telephone: (240)-276-6467; E-mail: david.lambertson@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

U.S. Provisional Patent Application 62/508,197 entitled "Anti-Mesothelin Polypeptides and Proteins" [HHS Ref. E-106-2017-0-US-01], PCT Patent Application

PCT/US2018/033236 entitled “Anti-Mesothelin Polypeptides and Proteins” [HHS Ref. E-106-2017-0-PCT-02], U.S. Patent Application 16/631,971 entitled “Anti-Mesothelin Polypeptides and Proteins” [HHS Ref. E-106-2017-0-US-03], U.S. Provisional Patent Application 63/290,761 entitled “Anti-Mesothelin Polypeptides and Proteins” [HHS Ref. E-033-2021-0-US-01], and U.S. and foreign patent applications claiming priority to the aforementioned applications.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The license to be granted may be worldwide, and may be limited to the following field of use:

“The development, production and commercialization of a mono-, bi-, or multi-specific anti-MLSN (Mesothelin) chimeric antigen receptor (CAR)-based allogeneic immunotherapy using genetically engineered, iPSC-derived human NK cells where the CAR has at least:

(1) The complementary determining region (CDR) sequences of the (humanized) anti-MSLN antibody known as 15B6;

(2) A transmembrane domain; and

(3) At least one signaling domain,

for the treatment of MSLN-expressing solid tumors.”

Mesothelin is a cell surface protein that is expressed on a number of types of cancer cells, including mesothelioma, pancreatic cancer, ovarian cancer, and certain lung cancers. There are currently few effective therapies for patients with these types of cancers, with many patients experiencing disease relapse. Upon relapse, there are even fewer second-line therapeutic options, underscoring an unmet patient need. The

development of an anti-mesothelin CAR-based therapy can potentially be used for the treatment of mesothelin-expressing cancers. As a result, the development of a new therapeutic option targeting mesothelin will benefit public health by providing an effective treatment for patients that might otherwise have no options.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 U.S.C. 552.

Dated: May 25, 2022.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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